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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,582	08/27/2003	James Brugger	53951-093	8937

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/649,582	BRUGGER ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-10,12,14,16-19 and 21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10,12,14,16-19 and 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 26 is objected to because of the following informalities: Line 3 sets forth "a fluid circuit with a blood processing filter a fluid input connector." For the purposes of examination , Examiner is interpreting the claim to incorporate a fluid circuit with a blood processing filter and a fluid input connector.. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 6, 7, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,476,592 to Simard in view of US 6,716,356 to Collins et al.

In the specification and the figures, Simard discloses the apparatus substantially as claimed by applicant. With regard to claims 1, 6, 26, 28, and 29, Simard discloses a hemofiltration apparatus with a fluid circuit with a blood path 5, 6, filtrate line 10 connected 3 across a porous membrane 4 to the blood portion 2, and a replacement fluid line 22 connected to the blood path. The entirety of the replacement fluid is passed through tubing that is connected to in-line sterile filter 24 for removing pyrogens (see FIG 1, column 2, lines 45-67, column 3, lines 1-20). The circuit comprises a drip chamber 8 with two inlets or connectors that allow the filtered blood (which may

comprise a replacement fluid, since it is replacing the fluid drawn into the circuit) and the substituate or replacement fluid to be connected to the return line 6. The device further comprises pump 7 in the blood draw line 5, pump 14 in filtrate line 10, and pump 23 in replacement fluid line 22.

Simard fails to disclose that the replacement fluid portion has a plurality of connectors joined to flow through the sterilizing filter and a common inlet to the replacement fluid portion. However, Collins discloses an extracorporeal fluid treatment circuit with replacement fluids that flow from sources 102, 152, and 150 that are connected to the replacement fluid line (see FIG 2, column 3, lines 25-33). Multiple containers are connected to the replacement fluid line to adjust the pH of the replacement fluid (see column 4, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add multiple fluid lines and connectors in the replacement fluid portion as disclosed by Collins to the extracorporeal treatment system disclosed by Simard in order to adjust the composition of the replacement fluid, as taught by Collins (see column 4, lines 20-25).

With regard to applicant's claim limitations drawn to "no intervening pumping portions between the junction and the sterilizing filter," such a limitation is not a patentably distinct variation from the prior art. It has been held that omission of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04(II)(A). In the instant case, the replacement fluid sources 102, 152, and 150 may all be connected to a flow controller 106 that meters the flow and concentration of fluid coming from those sources into the replacement fluid line (see Collins FIG 2).

Accordingly, pump 158 between the replacement fluid junction (at 106) may be eliminated, with all control of fluid flow through the filter being effected by controller 106. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to eliminate pump 158 between the fluid junction and the filter, since the controller 106 is capable of delivering fluid to filter 160/171.

Applicant presents claims drawn to a "kit" of the claimed components. However, applicant has not set forth in the specification what, exactly, comprises the kit, other than the claimed components. Therefore, examiner has interpreted the claims to mean that the claimed components comprise the claimed kit.

With regard to claim 7, Simard discloses filtrate line with pump 14, blood line with pump 7, and replacement fluid line with pump 23, each of which are configured to interact with one another to move fluids through the lines (see FIG 1, column 2, line 45 through column 3, line 15).

With regard to claim 27, the prior art is silent with regard to the length of the tubing lines connecting to the sterilizing filter. However, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). In the instant case, it does not appear that the length of the fluid tubing in the prior art has a significant effect on the functions of the devices. Absent a showing by Applicant of the

criticality of the length of the tubing lines, the limitation is not considered by the Examiner to patentably distinguish from the prior art.

4. Claims 3, 5, 8-10, 12, 14, 16-19, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,476,592 to Simard in view of US 6,716,356 to Collins, further in view of US 5,441,636 to Chevallet et al.

In the specification and figures, Simard and Collins disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a cassette, support or tray that supports the fluid circuit, filter, and other components.

With regard to claims 3, 8, Chevallet discloses a fluid handling plate or tray 20 that may comprise multiple interconnected fluid circuits, including a blood supply and return line, a dialyzer, diasylate circuit, and a replacement fluid circuit (see FIGS 1-2, column 4, lines 3-67). The placement of all the components in a support or cassette allows for reduced pre and post-procedure handling and connection, reducing connection errors, and lends itself to sterile packaging and safe disposal (see column 2, lines 1-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the fluid lines, filters, and pumps disclosed by Simard and Collins in a support cassette as disclosed by Chevallet, in order to reduce preparation time and errors, as taught by Chevallet (see column 2, lines 1-8).

With regard to claim 5, Chevallet specifically discloses that the replacement fluid circuit 80 comprises bag spike 81 for selective connection to a fluid source (see column 4, lines 56-65). Simard and Collins teach a fluid circuit with a replacement fluid circuit comprising a plurality of connections to multiple fluid sources and Chevallet teaches the

use of a spike to make such a connection. The combination of the disclosures suggest that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of bag spikes as connectors to multiple fluid sources, since Chevallet teaches that such a connection is well-known in the art (see column 4, lines 56-63).

With regard to claims 9 and 12, Simard and Collins disclose an extracorporeal fluid circuit with an inline sterile filter in the replacement fluid line and multiple connections to multiple fluid sources, as set forth above. Chevallet specifically discloses a support plate or cartridge 20 with a plurality of fluid circuits mounted therein (see column 4, lines 3-25). The fluid circuits include a dialyzer or filter 40 with a blood circuit portion 50, 70, connected to the filter, as well as a replacement fluid circuit 80 and a waste fluid circuit 100 (see column 4, line 3 through column 5 line 23).

With regard to claim 10, Simard discloses a venous line connected to a patient access (see column 2, lines 50-55) and illustrates filter 15 as disposed between fluid source 11 and blood circuit 5/6, with the replacement fluid line 22 connected via drip chamber 8 to venous return line 6 (see FIG 1).

With regard to claim 14, Chevallet specifically discloses that the replacement fluid circuit 80 comprises bag spike 81 for selective connection to a fluid source (see column 4, lines 56-65). Simard and Collins teach a fluid circuit with a replacement fluid circuit comprising a plurality of connections to multiple fluid sources and Chevallet teaches the use of a spike to make such a connection. The combination of the disclosures suggest that it would have been obvious to one having ordinary skill in the

art at the time the invention was made to use a plurality of bag spikes as connectors to multiple fluid sources, since Chevallet teaches that such a connection is well-known in the art (see column 4, lines 56-63).

With regard to claim 16, Simard discloses filtrate line with pump 14, blood line with pump 7, and replacement fluid line with pump 23, each of which are configured to interact with one another to move fluids through the lines (see FIG 1, column 2, line 45 through column 3, line 15).

With regard to claim 17, Chevallet illustrates that support or tray 20 comprises connectors 34 that align the pumping tube portions such that they may engage with roller pumps or actuators 112, 113, 114, 115 on a treatment module.

With regard to claims 18, 21, 23, Simard and Collins disclose an extracorporeal fluid circuit with an inline sterile filter in the replacement fluid line and multiple connections to multiple fluid sources, as set forth above. Chevallet specifically discloses a support plate or cartridge 20 with a plurality of fluid circuits mouted therein (see column 4, lines 3-25). The fluid circuits include a dialyzer or filter 40 with a blood circuit portion 50, 70 connected to the filter, wherein the blood circuit may be configured for both venous and arterial blood supply and return arrangements, meeting the limitations of the claim (see coumn 3, lines 23-35). The fluid circuit further includes a replacement fluid circuit 80 connected to a replacement solution and an outlet end optionally connected to blood return circuit (see column 4, lines 56-68).

With regard to claim 19, Simard discloses that the filter has a porosity of 0.22μm (see column 3, lines 56-62), meeting the limitations of the claim.

With regard to claim 22, Chevallet specifically discloses that the replacement fluid circuit 80 comprises bag spike 81 for selective connection to a fluid source (see column 4, lines 56-65). Simard and Collins teach a fluid circuit with a replacement fluid circuit comprising a plurality of connections to multiple fluid sources and Chevallet teaches the use of a spike to make such a connection. The combination of the disclosures suggest that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of bag spikes as connectors to multiple fluid sources, since Chevallet teaches that such a connection is well-known in the art (see column 4, lines 56-63).

With regard to claim 24, Simard discloses filtrate line with pump 14, blood line with pump 7, and replacement fluid line with pump 23, each of which are configured to interact with one another to move fluids through the lines (see FIG 1, column 2, line 45 through column 3, line 15).

With regard to claim 25, Chevallet illustrates that support or tray 20 comprises connectors 34 that align the pumping tube portions such that they may engage with roller pumps or actuators 112, 113, 114, 115 on a treatment module.

Response to Arguments

5. Applicant's amendment and arguments filed 5 April 2007 have been entered and considered.

6. Applicants arguments with respect to the pending claims have been considered but are not persuasive.

7. Applicant argues that the prior art does not teach a plurality of fluid connections to the sterilizing filter with "no intervening pumping portions between the junction and the sterilizing filter," such a limitation is not a patentably distinct variation from the prior art. It has been held that omission of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04(II)(A). In the instant case, the replacement fluid sources 102, 152, and 150 may all be connected to a flow controller 106 that meters the flow and concentration of fluid coming from those sources into the replacement fluid line (see Collins FIG 2). Accordingly, pump 158 between the replacement fluid junction (at 106) may be eliminated, with all control of fluid flow through the filter being effected by controller 106. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to eliminate pump 158 between the fluid junction and the filter, since the controller 106 is capable of delivering fluid to filter 160/171.

8. Applicant further argues that the prior art does not disclose a system whereby the entirety of the replacement fluid passes through the sterilizing filter. However, in the embodiment shown in FIG 2 of Collins, all of the fluid flowing into the replacement fluid line is required to pass through filters 160/171 en route to connector line 136. Accordingly, the disclosures of the prior art meet the limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
6 June 2007